IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

BRIAN JOHNSON, on Behalf of Himself and All Others Similarly Situated, Plaintiff(s), v. POZEN INC., JOHN R. PLACHETKA, MARSHALL REESE, WILLIAM L. HODGES, and PETER J. WISE, Defendant(s).	)	**MEMORANDUM OPINION, RECOMMENDATION, AND ORDER** 1:07CV599

This matter is before the court on a motion to dismiss filed by Defendants Pozen Inc., John R. Plachetka, Marshall Reese, William L. Hodges, and Peter J. Wise (docket no. 50).[1] Also pending before the court is a request by the moving Defendants for judicial notice of certain documents attached to the motion to dismiss (docket no. 56), as well as a corresponding motion filed by Plaintiffs to strike various exhibits attached to Defendants' motion to dismiss (docket no. 59). Also before the court is a request for oral argument on the motion to dismiss filed by Defendants (docket no. 58). Finally, Plaintiffs have requested that, in the event the Amended

[1] Also referred to the court was a pending motion to dismiss filed separately by Defendant Peter Wise on June 26, 2008 (docket no. 52). On August 27, 2008, Plaintiffs voluntarily dismissed Wise as a Defendant pursuant to Rule 41(a)(1) of the Federal Rules of Civil Procedure (docket no. 64). Therefore, the separate motion to dismiss by Defendant Wise has been rendered moot.

Complaint does not allege a claim for securities fraud, they be given the opportunity to amend the Amended Complaint.

BACKGROUND

This is a class action lawsuit in which the plaintiff investors are suing a pharmaceutical company and several of its officers for securities fraud. Lead Plaintiffs Plumbers' Union Local No. 12 Pension Fund and Gilbert Rodriguez bring this securities class action on behalf of themselves and a Class consisting of all purchasers of the publicly traded securities of Pozen Inc. between July 31, 2006, and August 1, 2007, inclusive (the "Class Period"), against Pozen and certain of its top officers seeking to recover damages caused by Defendants' alleged violations of federal securities laws and to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). (*See* Amended Compl., docket no. 47.) Plaintiffs allege specifically that their claims arise under and pursuant to sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5). The Amended Complaint names as Defendants Pozen and several of its top officers, including CEO John Plachetka. Defendants have filed a motion to dismiss the complaint.

Plaintiffs' Motion to Strike Defendants' Exhibits on Defendants' Motion to Dismiss

I first note that Plaintiffs have filed a motion to strike various exhibits attached to Defendants' motion to dismiss. These exhibits include, among other things, SEC filings, newspaper articles, Pozen press releases, transcripts from conference calls,

and a public FDA guidance. Defendants have requested that the court take judicial notice of these exhibits. In support of the motion to strike the exhibits, Plaintiffs primarily argue that these exhibits are not properly before the court on a motion to dismiss. Plaintiffs request that the court strike these documents; alternatively, Plaintiffs ask the court to allow further discovery and to convert the motion to one for summary judgment.

Plaintiffs' motion to strike is denied. As Defendants note, because the motion to dismiss is brought in a securities fraud case that is governed by the pleading standards of the Private Securities Litigation Reform Act ("PSLRA"), the strict requirements of a typical Rule 12(b)(6) motion do not apply. That is, the court may and must consider a plaintiff's allegations in a securities fraud case in the context of the entire record. Indeed, in light of the recent Supreme Court case of *Tellabs, Inc. v. Makor Issues & Rights, Ltd.,* 127 S. Ct. 2499 (2007), this circuit's court of appeals has observed:

> Plaintiffs insist that we should rely solely on their discrete allegations, and they urge us not to look beyond the complaint for additional facts. In particular, the complaint quotes selectively from various reports by investment analysts, and plaintiffs argue that we should not consider the reports in full. That argument is erroneous. While we must accept plaintiffs' factual allegations as true, the Supreme Court in *Tellabs* held that we should not decide the issue of scienter by viewing individual allegations in isolation. Rather, we must examine the facts as a whole, including facts found in "documents incorporated into the complaint by reference." *Id*. Furthermore, plaintiffs nowhere challenge the authenticity of the analyst reports attached to defendants' motion to dismiss and cited in plaintiffs' complaint. Our consideration of such documents is undoubtedly proper.

Cozzarelli v. Inspire Pharms., Inc., 549 F.3d 618, 625 (4th Cir. 2008).

Significantly, here, Plaintiffs do not dispute the accuracy of any of the exhibits submitted by Defendants on the motion to dismiss. Furthermore, the exhibits at issue are either explicitly referenced in the complaint, part of the public record, or included in the information that was publicly available to investors at the time of the alleged fraud. Here, Plaintiffs are alleging "fraud on the market." (*See* Amended Compl. ¶¶ 154-55.) As Defendants note, in securities fraud cases courts routinely take judicial notice of newspaper articles, analysts reports, and press releases in order to assess what the market knew at particular points in time, even where the materials were not specifically referenced in the complaint. *See, e.g., In re Inspire Pharms., Inc. Sec. Litig.*, 515 F. Supp. 2d 631, 637 (M.D.N.C. 2007) (assessing the plaintiffs' falsity allegations in light of pre-class period disclosures by defendants and analyst reports describing clinical trial results); *Benak v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006) (taking judicial notice of newspaper articles to establish what the market knew).

As this circuit's court of appeals noted in *Cozzarelli*, the Supreme Court in *Tellabs* clarified that in a securities fraud case a court must consider alleged false statements in the context of the entire record, and this may include the same types of documents that Defendants have presented to support their motion to dismiss. Therefore, I will deny the motion to strike and consider the motion to dismiss in light

of all of the evidence in the record.[2] The following facts, while taken primarily from Plaintiffs' Amended Complaint, also incorporate various exhibits presented by Defendants in support of the motion to dismiss.

FACTS

Defendant Pozen is a pharmaceutical company with its principal place of business in Chapel Hill, North Carolina. (Amended Compl. ¶ 16.) Pozen develops innovative drugs to treat pain in partnership with larger pharmaceutical companies such as Glaxo SmithKline ("GSK"). (*See id.* ¶¶ 2-3; 32-33.) During the Class Period–between July 31, 2006 and August 1, 2007–the lead migraine drug being sold in the U.S. market was Imitrex, which was marketed by GSK. Imitrex was set to lose its patent protection, however, by February 2009. Therefore, GSK was hoping, with the help of Pozen, to market a new migraine drug before Imitrex lost its patent protection. (*See id.* ¶¶ 2-3; 40.)

The new drug that GSK sought to market was called Trexima, which is a combination of two drugs already approved by the FDA. The first is sumatriptan (or "triptan"), the migraine pain medication sold by GSK as Imitrex. (*Id*. ¶ 39.) The second is naproxen (a non-steroidal anti-inflammatory drug, or "NSAID"), an over-

[2] To this extent, I grant the moving Defendants' request to take judicial notice of the documents attached to the motion to dismiss. *See* FED. R. EVID. 201. Furthermore, I note that the Amended Complaint is 79 pages long with no less than 180 paragraphs. The parties have narrowed down the pertinent issues and facts in their respective briefs. I, therefore, will recite only the relevant facts and highlights of Plaintiffs' allegations regarding Defendants' alleged securities fraud.

the-counter pain medication sold under the name Aleve. (*Id*.) The two drugs complement each other in a manner that provides superior pain relief to either alone. (*Id*. ¶¶ 39, 57.) Pozen owns the patents on the combination of Imitrex and naproxen. (*Id*. ¶ 41.) More specifically, Pozen holds a patent on the clinical use of triptans and NSAIDs in combination; thus, any pharmaceutical company wishing to develop such a combination drug must go through Pozen. (*Id*.)

The GSK Partnership Agreement

In June 2003, Pozen signed an agreement with GSK for the development and commercialization of Trexima. (*Id.* ¶ 37.) Under the agreement, Pozen was responsible for the development of Trexima, while GSK was responsible for manufacturing and commercialization. (*Id*.) As part of the agreement, GSK agreed to pay Pozen upon the achievement of certain development, regulatory, and commercial "milestones," as well as royalties on sales. (*Id*. ¶ 38.) As of August 2007, GSK had paid Pozen approximately $60 million and agreed to pay $20 million more upon FDA approval of Trexima, with further payments and royalties, depending on Trexima sales volume. (Defs.' Ex. 27 to Porritt Decl., at 18, docket no. 54.)

The Drug Testing and Approval Process

Preclinical Testing and Genotoxicity

On average, it takes twelve years for an experimental drug to travel from the laboratory to a pharmacy. (Amended Compl. ¶ 43.) Testing on a potential new drug occurs in stages. First, a drug candidate is subjected to laboratory testing to identify

mechanism of action and determine safety. (*Id.* ¶ 44.) These tests are usually *in vitro*, meaning they occur in cell cultures or can be animal studies, and they are referred to as "preclinical" or "nonclinical" because they do not involve human testing. (*Id.*)

Preclinical tests take about three and a half years. If preclinical testing supports the safe use of the drug candidate in humans, the drug candidate may proceed to clinical, or human, testing. (*Id*. ¶¶ 45-50.) On average, only five in 5,000 compounds that enter preclinical testing ever make it to human testing. (*Id.*) Moreover, only one in every five drugs that makes it to human testing is ever approved. (*Id*.)

During preclinical testing, the drug's active ingredients are subjected to *in vitro* tests intended to evaluate whether the drug damages DNA. Agents that damage DNA are called genotoxicants and have the potential to cause cancer. (*See id*. ¶ 67.) There are several types of genotoxicity tests. One is the Chinese Hamster Ovary, or "CHO," test. (*Id*. ¶ 66.) The CHO test involves the introduction of extremely high doses of the drug candidate to cells originally derived from Chinese hamster ovaries. (*See* Defs.' Ex. 26 to Porritt Decl., at 9-10.) Because the extremely high doses of a drug can sometimes kill the cells that are to be evaluated, the CHO test is not always reliable. (Amended Compl. ¶ 136; Defs.' Ex. 26 to Porritt Decl., at 8-10.)

A second type of genotoxicity test is the mouse lymphoma assay, which is reliable enough to be "considered an acceptable alternative to the direct analysis of chromosomal damage in vitro." (*Id.* ¶ 68 n.3.) The fact that a drug candidate yields a positive result in one type of test is not definitive. Rather, the FDA will examine whether there is evidence confirming this result, such as from another type of test. (Defs.' Ex. 6 to Porritt Decl., at 2-3.) In a January 2006 "Guidance for Industry and Review Staff" titled *Recommended Approaches to Integration of Genetic Toxicology Study Results* (hereinafter the "FDA guidance"), the FDA has stated that with regard to positive results in a CHO study, "a positive finding in an *in vitro* chromosomal aberration assay that is not corroborated by the matching exposure regimen of the mouse lymphoma assay could also call into question the significance of the positive finding." (*See* Defs.' Ex. 6 to Porritt Decl., at 3.) In other words, a positive result in a CHO study is not necessarily significant if the mouse lymphoma assay yields a negative result.

The IND after Preclinical Testing

After completing preclinical testing, the company files an Investigational New Drug Application ("IND") with the FDA to begin to test the drug in humans. (Amended Compl. ¶ 45.) The IND automatically becomes effective as long as the FDA does not disapprove it within thirty days after filing. (*Id*.) The IND shows results of previous experiments, how, where, and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the

body; any toxic effects found in the animal studies; and how the compound is manufactured. (*Id.*)

Clinical Trials

After the IND becomes effective, the company developing the new drug conducts three phases of clinical trials, which progressively involve more patients and longer durations and study the drug's efficacy and safety. (*See id.* ¶ 46.) A clinical trial is a comparison test of a medication versus a placebo, other medications, or the standard medical treatment for a patient's condition. (*Id*.) Phase I clinical trials study a drug's safety profile, including the safe dosage range. (*Id.* ¶ 48.) The Phase I studies also determine how a drug is absorbed, distributed, metabolized, and excreted, and the duration of its action. (*Id*.) Phase I clinical trials take about a year and involve about 20 to 80 normal, healthy volunteers. (*Id*.)

After the Phase I clinical trials are conducted, Phase II clinical trials begin. In Phase II, controlled studies of about 100 to 300 volunteer patients assess the drug's effectiveness. (*Id.* ¶ 49.) Finally, Phase III clinical trials are conducted on the new medication. Phase III trials last about three years and usually involve 1,000 to 2,000 patients in clinics and hospitals, with doctors monitoring patients closely to determine efficacy and to identify adverse reactions. (*Id.* ¶ 50.)

After completion of all three phases of clinical trials, the company analyzes all of the data and–assuming the data successfully demonstrate safety effectiveness–files a New Drug Application ("NDA") with the FDA. (*Id.* ¶ 51.) The

NDA must contain all of the scientific information that the company has gathered regarding the medication. By law, the FDA is allowed six months to review the NDA. (*Id.* ¶ 51.) Review of the NDA is generally the last step in the approval process; if the NDA is approved, the drug can then be marketed and sold.

In 2002, Pozen Receives a Positive Result for Genotoxicity during Preclinical Testing

The test results at issue in this case were from tests conducted during *preclinical* testing, as described above. In 2002, Pozen ran three genotoxicity tests on Trexima, which was called "MT-400" at that stage of the drug's development. Two of the genotoxicity tests yielded negative results (i.e., no potential to cause cancer). One of the tests, however–the CHO test–yielded a positive result (i.e., potential to cause cancer). (*Id.* ¶ 66; Defs.' Ex. 26 to Porritt Decl., at 15.) Pozen warned investors in its November 2002 Form 10-Q that the CHO study raised potential genotoxicity concerns, by stating "recent results from a genotoxicity study involving MT 400 may require us to conduct chronic toxicology and carcinogenicity studies." (Defs.' Ex. 1 to Porritt Decl., at 9.)

Despite the positive CHO test result, Pozen was allowed to proceed with clinical trials, which showed Trexima to be effective in treating migraines. (Amended Compl. ¶¶ 53-57.) Pozen filed a NDA for Trexima on August 8, 2005. (*Id*. ¶ 58.) The CHO test result was included in the NDA. (Defs.' Ex. 26 to Porritt Decl., at 6.)

The June 2006 Approvable Letter

On June 9, 2006, Pozen received an approvable letter from the FDA. (Amended Compl. ¶ 59.) An approvable letter states that if the drug sponsor can satisfy certain conditions, its NDA may be approved. (*Id*.) These conditions can typically range from small discussions on labeling to requirements for further clinical studies, with a consequent delay of weeks or months for a product launch. (*Id*.) The Approvable Letter dated June 9, 2006, requested additional information regarding Trexima's cardiovascular safety.[3] (*Id.* ¶ 65.) The Approvable Letter also instructed Pozen to perform additional, *nonclinical* studies regarding genotoxicity. (*Id*. ¶¶ 61, 68.) These additional studies included a second CHO study, plus a mouse lymphoma TK assay. (*Id*.)

On July 26, 2006, Pozen and GSK met with the FDA to discuss the requests made in the Approvable Letter. (*Id.* ¶ 69.) At that time, GSK was completing its Phase IIIb clinical studies, which included a study involving 1,700 additional Trexima patients. (*Id.*) The study showed no serious cardiovascular adverse events, and the FDA agreed to accept this additional study, but the FDA also requested certain

[3] More specifically, the FDA noted that the rate of vasospasm for Trexima appeared to be higher than the other drugs in the class of triptan-based migraine medicines. (Amended Compl. ¶ 61.) As the Amended Complaint explains, coronary vasospasm, or coronary artery spasm, refers to the narrowing of a blood vessel, usually an artery, by tightening or spasm of the muscles within the vessel's wall. (*Id*.) This narrowing imposes a restriction in the volume of blood flowing through the vessel. (*Id*.) As a result, coronary artery spasm can cause shortness of breath and chest tightness. (*Id*.) Generally, vasospasm is considered a class effect of all triptan-based migraine medications.

information on Imitrex to fulfill the additional data requested in the 2006 Approvable Letter. (*Id.*) Specifically, the FDA required a more detailed analysis of patient baseline characteristics to compare Trexima's safety profile to that of Imitrex. (*Id.*)

The Class Period begins on July 31, 2006. (*Id.* ¶ 89.) On that date, Pozen issued a press release titled "Pozen to Submit Full Response to Trexima Approvable Letter During the Fourth Quarter." (*Id.*) The press release noted that Pozen planned to submit a full response to the Approvable Letter and that the response would include additional "safety" information that had been requested by the FDA. (*Id*.) The July 31, 2006, press release did not specifically mention the FDA's concerns over "genotoxicity" or the results of the CHO Study. (*See id.*)

As a result of the press release dated July 31, 2006, Pozen's stock price rose 27 percent to $10.55 per share. (*Id.* ¶ 90.) The *Raleigh News & Observer* newspaper noted that "analysts and investors considered the announcement to be an encouraging sign that the migraine treatment may come to market next year." (*Id.*) Plaintiffs allege that the investment community interpreted the information in the press release as positive news for Pozen, given the likelihood that the Company would not have to conduct any new clinical trials. (*Id.* ¶ 91.) On August 1, 2006, Wachovia Securities wrote to investors that "[w]e view this as potentially good news for POZN, as the fairly quick turnaround on the submission suggest[s] no new clinical studies are necessary, and POZN likely has the requisite safety data already in its possession." (*Id*.) On that same date, HSBC Global Research issued an

analyst report titled, "A Significant Step on the Road to Trexima," in which HSBC advised investors that the time line on the Trexima submission indicated that "no further safety trials are needed to complete the full response." (*Id.*)

On August 3, 2006, during an investor conference call, Pozen disclosed that it would be performing two *in vitro* studies regarding Trexima (referring to the CHO study and the mouse lymphoma assay regarding genotoxicity), and that it would submit those results along with the cardiovascular data that the FDA had requested. (*Id*. ¶ 92.) In the conference call CEO Plachetka discussed Pozen's response to the Approval Letter and stated, in part, that "[o]ur cash position should improve assuming Trexima approval in 2007 which generates our $20 million milestone payments along with royalties for whatever portion of the year Trexima is marketed." (*Id*.) Plachetka further stated in the conference call:

> Let's turn to Trexima for a few minutes. The approval letter was received on the expected . . . date, . . . the FDA acknowledges the efficacy criteria had been met. So that question was taken away. At the same time, *the FDA requested some additional information relating to . . . safety . . . of Trexima before final approval could be granted*.
>
> Now the update in progress since then, we've met with the FDA July 26, showed them some of the new clinical safety data that we intend to submit and agreed upon a response framework that we and they feel should successfully address the question. Of course, there is never any guarantee that this response will be adequate and it's always possible that additional questions could arise during their review. But as of now we and GSK feel very good about the response we are preparing.
>
> The majority of the new clinical safety information comes from Phase IIIb clinical trials already completed by GSK but not yet compiled in the

> final report. We're putting that data into the agreed designated format the FDA requested in order to facilitate their review of it so we're cooperating closely with GSK on the construction of this response. As to the question of what other safety information is being included, *I can tell you that two in vitro nonclinical studies are being conducted and those results will be included in the response also*.

(*Id.*) (emphasis added). Thus, Plachetka referred to the nonclinical studies–the CHO study and the mouse lymphoma assay–regarding genotoxicity in the conference call, although he did not specifically use the word "genotoxicity" in referring to the studies, nor did he specifically discuss the prior genotoxicity findings.

Defendant Plachetka also went on to state in the conference call that he was "confident" that the FDA would approve Trexima sometime in the second quarter of 2007, stating, "I think mid year is a pretty reasonable best case for this action." (*See id.* ¶ 93.) According to Plaintiffs, Plachetka "further conditioned the market to expect FDA approval for Trexima in 2007" when he told *BioWorld* that Pozen had "a very clear path to follow at FDA," adding that Defendants had "shown them most of the data that we're going to put in our full response, and after seeing that data, they said they didn't need any new data, which was great." (*Id.* ¶ 94.) Finally, Plaintiffs also note that in the August 3, 2006, investor conference call regarding the anticipated launch date of Trexima, Pozen's CFO Bill Hodges stated, "As a developmental stage company, one of the things you learn early is that cash is king and that you want to have more money in the bank than you need to spend . . . . [W]ith the expected

approval of Trexima in May 2007 . . . our cash and profitability will continue to improve." (*Id.* ¶ 92.)

On September 20, 2006, Pozen issued another press release, summarizing the results of Pozen's ongoing studies that were undertaken because of the 2006 Approvable Letter. The press release stated, among other things, that Trexima was well tolerated across both studies and that adverse events were "generally mild with the most common being dry mouth, nausea, and dizziness across all attacks treated in both studies" and that "[n]o serious drug-related adverse events were reported." (*Id.* ¶ 96.) Also on September 20, 2006, Pozen issued another press release touting the efficacy of Trexima when taken at the first onset of a migraine and reiterating that Trexima was "well tolerated" in all studies. (*Id.* ¶ 97.) Plaintiffs allege that Defendants' "false and misleading" statements were intended to counter the impact of the 2006 Approvable Letter and that they succeeded, resulting in positive reports from analysts and a further rise in the Company's stock prices. (*Id.* ¶¶ 98-99.)

On October 31, 2006, Pozen released its third quarter financial results and made further statements regarding the status of the Trexima NDA during an analyst conference call. (*Id.* ¶ 100.) In the conference call, Plachetka noted that the Company was submitting additional safety information, including the results from the two *in vitro* nonclinical studies, in response to the FDA's approval letter. Plachetka predicted that the Company would submit its response by November 2006 and that the Company anticipated a six-month review, which would give an FDA approval

date of sometime late in the second quarter of 2007. (*Id.*) Plachetka went on to state that "assuming that Trexima is approved in mid 2007, we expect to receive the $20 million milestone payment [from GSK], along with royalties for whatever portion of the year Trexima is marketed . . . . Therefore, we expect to remain in a pretty solid cash position next year." (*Id.*) Plachetka further continued to tout Trexima as a blockbuster drug, and Pozen stock rose as a result. (*Id.* ¶¶ 100-04.)

When Pozen and GSK conducted the second CHO study, the CHO study again produced a positive result at very high dosages. (*Id.* ¶ 70.) The mouse lymphoma test, however, produced a negative result. (*Id*. ¶ 136.) Defendants did not disclose in either the October 31, 2006, conference call or the subsequent press release that the second CHO study had yielded another positive result. Indeed, as noted previously, Defendants did not refer specifically to "genotoxicity" at all when discussing in conferences and press releases that further *in vitro* studies were being conducted.

In February 2007, Defendants submitted the results of both *in vitro* tests to the FDA, along with the cardiovascular data. (*Id.* ¶ 112.) Once its response was accepted by the FDA, the expected FDA action date was clarified as August 1, 2007. (*Id*. ¶ 115.) Defendants also disclosed Pozen's revenue forecasts, assuming Trexima approval in August 2007, with a launch of the drug later that year. (*Id*. ¶¶ 93, 108, 111-12, 121.) Like Defendants, GSK also announced that it anticipated a Trexima launch in the second half of 2007. (*Id.* ¶¶ 112-13.) Based on GSK's

statements regarding the anticipated date of FDA approval in August 2007, analysts were bullish about Pozen stock, predicting among other things that "Trexima will be the new gold standard treatment of migraine headaches" and that Trexima would capture significant market share in the migraine market by converting its sales to Trexima before the patent ran out on Imitrex. (*See id.* ¶ 130.)

The August 2007 FDA Approvable Letter

As it turns out, the FDA did not approve Trexima on the anticipated date of August 1, 2007. Instead, on August 1, 2007, Pozen received a second FDA Approvable Letter for Trexima. This letter did not request any additional cardiovascular information, but it did require Pozen to further address the positive CHO test results regarding genotoxicity before approval could be granted. (*Id.* ¶ 133.) Pozen disclosed the letter to the public on August 2, 2007. (*Id.*) On that day, Pozen's stock price decreased by about 43 percent (from $17.45 to $9.23), on abnormally high trading volume, when it became clear that Trexima was not going to be approved on the anticipated date. (*Id.* ¶ 159.) According to Plaintiffs, "the rapid decline in Pozen's stock price following the August 2, 2007, revelations was a direct and foreseeable consequence of the revelation of the falsity of Defendants' Class Period misrepresentations and omissions to the market." (*Id.* ¶ 161.) Plaintiffs note that, in response to the second Approvable Letter, at least one analyst warned that GSK could decide to "scrap" the Trexima program altogether if there was much more delay in obtaining approval because a later approval would shorten the amount

of time that GSK had to switch patients to Trexima before the patent on Imitrex ran out. (*Id.* ¶ 135.)

Plaintiffs further note that during an August 2, 2007, investor conference call with investors and analysts, Defendant Plachetka admitted that the genotoxicity issue was not a surprise to Pozen, stating:

> Well, they asked us to do [two] in vitro studies in the [June 2006] approvable letter . . . and this was essentially a repeat of the [CHO] test. And then a second study which was also a gene tox study that if it had turned out positive, it would have essentially said yes, now, you have two tests that are positive. But in this situation what I have been told by experts is when you have one positive test, you look at the whole battery. And it was our interpretation that as the Agency asked us to do a second test and we already had another–I think we had another two already in the NDA that were negative, that if we ended up confirming that this was unique to the CHO test, which it appears to be unique to the CHO test, and negative in the other three tests that our experts and GSK's experts are saying that is just an anomaly of the way that the compound interacts in that particular test.
>
> And it does not foreshadow that this is going to be a problematic situation. And I think as I mentioned before, there are a high degree of positives in a particular test, but what the Agency has written about in their own guidance is that they look at where there is confirming gene toxicity in more than one test.
>
> So I don't want to say that this was a surprise. It wasn't a surprise. We knew this was there, but we also thought that this was not as important as the clinical issues [i.e., the cardiovascular test] because [the FDA] had spent most of their time talking about the clinical issue and because we had all of these offsetting negative results . . . . . [T]he new test that we did was called the mouse lymphoma test, and it was negative, but the study that was positive in our NDA, the [CHO] test which they cited in their approvable letter, was reproducibly positive. But again, we think that that is because during the course of this test as you raise the concentrations of the drugs, something kills the cells and that makes the data much more difficult to interpret.

> Now, I'm not a toxicologist and I don't want to start the discussion of what is right in the interpretation of data and how it all came about. But reasonable scientists have looked at these data and said, gee, I don't think [this] really indicates chromosomal problems here. This looks to me to be unique to this particular test.

(*Id.* ¶ 136.) Plaintiffs allege that analysts and the investing public were "shocked" by Plachetka's revelations regarding the genotoxicity tests "and quickly realized the Defendants had misrepresented or omitted material information." (*Id*. ¶ 137.) Plaintiffs note, for instance, that on August 2, 2007, *TheStreet.com* Senior Writer Adam Feuerstein, in an article titled "Pozen Pounded on FDA's Trexima Delay," wrote:

> I spoke this morning with a hedge fund analyst who was short Pozen going into Thursday's decision because she believed safety concerns would hold up approval. Now, she wasn't counting on potential chromosome damage as being the direct cause for an FDA rejection, but she did believe that neither Pozen nor [GSK] was completely transparent about the reasons for Trexima's first approvable letter in June 2006.

(*Id.* ¶ 137.) Moreover, on August 3, 2007, an analyst noted in his report that

> . . . the key safety concern that formed the basis for the company's second approvable decision [was] signs of genotoxicity observed with Trexima in a single type of in-vitro assay. Even though the company disclosed yesterday that this FDA concern arose even during the 1st FDA approvable decision, this was not relayed clearly to investors, in our view, prior to yesterday's announcement.

(*Id.* ¶ 138.)

Treximа Receives FDA Approval in April 2008

In response to the FDA's second Approvable Letter, Pozen and GSK submitted results of three additional *in vitro* studies on October 15, 2007. (Defs.' Ex. 28 to Porritt Decl.) Pursuant to the FDA's suggestion, Pozen and GSK also conducted a short-term, human volunteer study, and submitted the results to the FDA on January 15, 2008. (*Id*.; Ex. 29.) The FDA approved Trexima on April 15, 2008, and GSK made the $20 million milestone payment on April 28, 2008. (*See* Amended Compl. ¶ 9 & Ex. 30.) Trexima is currently being marketed under the brand name Treximet. (*See* Ex. 29.)

As noted, Trexima was ultimately approved by the FDA in April 2008. Plaintiffs, therefore, *do not contend* in this lawsuit that Defendants made false statements regarding whether Trexima would receive FDA approval. Rather, Plaintiffs' allegations center around Defendants' representations and predictions regarding *when* Trexima would be approved as well as Defendants' silence regarding results of the *in vitro* genotoxicity tests that ultimately pushed the anticipated approval date of August 2007 to April 2008. Plaintiffs allege that "Defendants' fraudulent scheme and false statements artificially inflated Pozen's stock price by failing to disclose that approval of Trexima by the FDA was not likely to occur during August 2007." (Amended Compl. ¶ 156.) Plaintiffs contend that by issuing false and misleading statements regarding the anticipated launch of Trexima in mid-2007, Defendants caused Pozen's stock to trade at artificially inflated levels

throughout the Class Period, "causing millions of dollars of damages to the Class when the truth was revealed and the artificial inflation was released from Pozen's stock price." (*Id.* ¶ 140.) Plaintiffs also allege that Defendants concealed the following "true facts" that Defendants allegedly omitted in their representations regarding Trexima and its anticipated launch date of August 2007:

> (a) Preclinical test data that Pozen had provided to the FDA raised serious questions as to whether combining sumatriptan and naproxen, the two components of Trexima, increased the risk of chromosomal or gene damage–which made it highly unlikely that the FDA would be able to thoroughly vet the safety issues within the six month time frame prescribed by law to review Defendants' submission/response to the 2006 Approvable Letter;
>
> (b) The approvability of the NDA for Trexima in mid-2007 was in serious doubt since the clinical study data submitted fell far short of current FDA standards;
>
> (c) Defendants knew but concealed from the market that their agreement with the FDA in July 2006 included a promise to conduct additional testing on Trexima's effects on blood pressure, rendering their July 2006 statements that no further testing was required for approval false and misleading;
>
> (d) Safety studies required to properly address the adverse effects of Trexima would substantially increase development costs for and FDA risks of non-approval in mid-2007;
>
> (e) The approvability of the NDA for Trexima by a date certain was further complicated by the strict regulatory environment following the VIOXX withdrawal;
>
> (f) Even if/when Trexima received approval, Defendants' market checks with physicians had revealed that only half were planning to prescribe Trexima to their patients, and then to only 25 % of their patients, in part because payors were likely to saddle Trexima with a high co-payment;

> (g) As a result of the factors detailed in (a)-(f) above, Defendants knew or had reason to know the Company would not receive $20 million in milestone payments or additional royalties during fiscal [year] 2007 and that Trexima would not add to Pozen's 2007 revenues or profitability and as a result the Company's stock was overvalued in the market; and
>
> (h) Any significant delay in Trexima receiving approval (whether resulting from the FDA's request for additional information/testing, the need to fully vet possible safety issues, and/or the regulatory environment post-VIOXX) would materially compromise the potential commercial success of Pozen's "niche product" as it would not have sufficient time to establish itself as Imitrex's successor prior to generics flooding the market.

(*Id*. ¶ 114.)

DISCUSSION

Plaintiffs' Claims Pursuant to Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5

Plaintiffs allege specifically that their claims arise under and pursuant to sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5). Under section 10(b) of the Exchange Act, it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe . . . ." 15 U.S.C. § 78j(b). Pursuant to section 10(b), the SEC has promulgated Rule 10b-5, which makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the

> light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. Section 10(b) creates a private right of action for purchasers or sellers of securities who have been injured by the statute's violation. *See, e.g., Superintendent of Ins. of State of N.Y. v. Bankers Life & Cas. Co.*, 404 U.S. 6, 13 n.9 (1971). Moreover, section 20(a) of the Exchange Act provides that

> [e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). Here, Plaintiffs seek to impose joint and several liability against the individually named Defendants, all officers of Pozen, as "controlling persons" under section 20(a).

To establish securities fraud liability under section 10(b) of the Exchange Act and Rule 10b-5, a plaintiff must prove that the defendant (1) made a false statement or omission of material fact (2) with scienter (3) upon which the plaintiff justifiably relied (4) that proximately caused plaintiff's damages. See *In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 387 (4th Cir. 2005). A fact is material "if there is a substantial likelihood that a reasonable purchaser or seller of a security (1) would consider the fact important in deciding whether to buy or sell the security or (2)

would have viewed the total mix of information made available to be significantly altered by disclosure of the fact." *Id.* Scienter may be proven by either intentional misconduct or recklessness, but not mere negligence. *Id.*

Standard of Review–Pleading Standards under the PSLRA

Because section 10(b) of the Exchange Act prohibits fraud, claims brought pursuant to that section have historically been governed by Rule 9(b) of the Federal Rules of Civil Procedure, rather than under Rule 8. Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). Rule 9(b) is an exception to the general requirement under Rule 8(a) that a plaintiff need only set forth a "short and plain statement of the claim" showing that the plaintiff is entitled to relief. *See* FED. R. CIV. P. 8(a).

Because courts had inconsistently applied Rule 9(b) in securities fraud lawsuits, in 1995 Congress enacted the PSLRA in an effort to strengthen and clarify pleading requirements and to discourage frivolous securities claims. Specifically, the PSLRA states in pertinent part that, with regard to a private action based on misleading statements and omissions,

> the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b)(1). Thus, the PSLRA requires plaintiffs to plead specific facts to support any claim of material misrepresentation under section 10(b) of the Exchange Act or Rule 10b-5. The PSLRA goes on to state:

> In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

Id. § 78u-4(b)(2). The PSLRA further states that "[i]n any private action arising under this chapter, the court shall, on the motion of any defendant, dismiss the complaint if the requirements of [the above two paragraphs requiring specific allegations of misleading facts and specific allegations of scienter] are not met." *Id.* § 78u-4(b)(3)(A). Finally, the PSLRA also provides that during the pendency of any private action brought under the PSLRA, "all discovery and other proceedings shall be stayed during the pendency of any motion to dismiss, unless the court finds upon the motion of any party that particularized discovery is necessary to preserve evidence or to prevent undue prejudice to that party." *Id.* § 78u-4(b)(3)(B).

Thus, in the context of a Rule 12(b)(6) motion, the PSLRA represents a clear departure from the general scheme of Rule 8(a). In 2007, the Supreme Court in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.* set forth three rules for applying the "strong inference" requirement of the PSLRA. 127 S. Ct. 2499 (2007). The Court held first that a court should "accept all factual allegations in the complaint as true."

Id. at 2509. The Court emphasized that the analysis should focus on allegations of facts and plausible inferences from those facts, observing that "omissions and ambiguities count against inferring scienter." *Id.* at 2511. Second, courts "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss," such as documents incorporated by reference or subject to judicial notice. *Id.* at 2509. Third, the scienter analysis necessarily requires courts to engage in a "comparative" inquiry, and a court addressing a motion to dismiss must consider "not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged." *Id.* at 2504. For an inference of scienter to be considered "strong," it must be "more than merely 'reasonable' or 'permissible'–it must be cogent and compelling, thus strong in light of other explanations." *Id.* at 2510.

With regard to the Supreme Court's interpretation of the PSLRA in *Tellabs,* this circuit's court of appeals very recently observed:

> To be sure, by no means did the PSLRA or the Supreme Court eliminate the private right of action in § 10(b), which remains "an essential supplement to criminal prosecutions and civil enforcement actions brought, respectively, by the Department of Justice and the [SEC]." *Tellabs*, 127 S. Ct. at 2504. The "strong inference" requirement is not meant to prevent litigants with meritorious claims from continuing to uncover fraud and ensure confidence in the securities markets. Rather, the requirement aims to weed out meritless claims at the pleading stage, without forcing defendants to go through a potentially costly discovery process.
>
> Thus, as directed by *Tellabs*, we must analyze the factual allegations raised by the plaintiffs, as well as other evidence in the

> record, and determine what plausible inferences we can draw from them. Having drawn all plausible inferences, we may reverse the district court only if we find the inference that [Defendants] acted with scienter "at least as compelling" as the inference that the defendants lacked the required mental state. In this endeavor, we "must consider plausible nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs*, 127 S. Ct. at 2510.

Pub. Employees' Ret. Ass'n of Colo. v. Deloitte & Touche LLP., No. 07-1704, 2009 WL 19134, at *7 (4th Cir. Jan. 5, 2009). With respect to the burden requiring proof of scienter, this circuit's court of appeals has held that a securities fraud plaintiff may allege scienter by pleading not only intentional misconduct, but also recklessness. *Ottmann v. Hanger Orthopedic Group, Inc.*, 353 F.3d 338, 344 (4th Cir. 2003). The issue before this court, then, on Defendants' motion to dismiss

> is whether the allegations in the complaint, viewed in their totality and in light of all the evidence in the record, allow [the court] to draw a strong inference, at least as compelling as any opposing inference, that [Defendants] either knowingly or recklessly defrauded investors . . . . If [the court finds] the inference that [D]efendants acted innocently, or even negligently, more compelling than the inference that they acted with the requisite scienter, [the court] must [grant Defendants' motion to dismiss].

Pub. Employees' Ret. Ass'n of Colo. v. Deloitte & Touche LLP., 2009 WL 19134, at *8.

Finally, in addition to the pleading standards, the PSLRA also includes a Safe Harbor provision to protect forward-looking statements, such as discussions of future plans, expectations, and financial projections. More specifically, forward-looking statements are immunized from liability if they contain "meaningful cautionary

statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement[s]." 15 U.S.C. § 78u-5(c)(1)(A)(i). Even if a forward-looking statement is not accompanied by cautionary language, liability *only* attaches if the speaker had *actual* knowledge that it was false when made. *Id.* § 78u-5(c)(1)(B)(i); *see also In re Lab. Corp. of Am. Holdings Sec. Litig.*, No. 1:03CV591, 2006 WL 1367428, at *3 (M.D.N.C. May 18, 2006). The PSLRA defines "forward-looking statement" to include "a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items," as well as "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer." 15 U.S.C. § 78u-5(i)(1). Furthermore, under Fourth Circuit law that predates the PSLRA, forward-looking statements are not actionable if they do not guarantee any particular results. *See Raab v. Gen. Physics Corp*., 4 F.3d 286, 290 (4th Cir. 1993). With these principles in mind, the court now addresses the parties' respective arguments on the motion to dismiss.

Plaintiffs' Allegations regarding Defendants' Alleged Fraudulent Statements and Failure to Disclose Material Facts regarding Trexima Approval during the Class Period

I first note that, in support of the motion to dismiss, Defendants characterize Plaintiffs' complaint as a "classic example of a 'puzzle-style' complaint," and

Defendants contend that dismissal is proper for this reason alone. (*See* Defs.' Br. 10.) Defendants contend, for instance, that Plaintiffs set forth lengthy block quotes from Pozen press releases, SEC filings, investor conference call transcripts, news articles, and analyst reports, but Plaintiffs never specify what portions of the statements they are challenging. Defendants note that after every few block quotes Plaintiffs simply include a paragraph that purports to identify the "true facts" on various topics that Defendants allegedly failed to disclose. According to Defendants, Plaintiffs never attempt to tie any specific "true fact" to any particular statement made by Defendants. Defendants note that the PSLRA requires Plaintiffs to identify with specificity the statements they allege are misleading and the facts that render those statements misleading, and Defendants contend that Plaintiffs' failure to make clear what portion of each quotation constitutes a false representation is clearly deficient under the PSLRA's stringent pleading standards. *See In re Alcatel Sec. Litig*., 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2005) ("Plaintiffs neglect to make it clear what portion of each quotation constitutes a false representation, or which statements link up with which issues in the laundry list, placing the burden on the Court to sort out the alleged misrepresentations and then match them with the corresponding adverse facts. This method is deficient under the pleading standards.").

In response to the motion to dismiss, Plaintiffs have winnowed down the statements made by Defendants that were allegedly false or misleading, and Plaintiffs' response makes clear that the gist of Plaintiffs' securities fraud case is

based on Defendants' failure to provide full disclosure regarding the genotoxicity results and tests; Defendants' repeated statements regarding purported lack of safety concerns by the FDA over Trexima and the overall safety of Trexima; Defendants' failure to disclose that there were "serious doubts" regarding the anticipated approval date of August 2007; and Defendants' statements regarding anticipated revenues in 2007 as a result of the anticipated August 2007 approval. To this extent, Plaintiffs appear to have abandoned their arguments that Defendants made false misrepresentations as to at least the "true facts" listed in (b), (c), (d), (e), (f), and (h), listed *supra*. For instance, Defendants contend, and Plaintiffs appear to concede, that Plaintiffs are not pursuing their fraud claims based on the fact that there was a strict regulatory environment after the withdrawal of Vioxx from the market or that physicians had stated that they did not intend to prescribe Trexima to their patients.[4] The court will, therefore, focus on the parties' arguments regarding the genotoxicity tests. To this extent, the court narrows its focus to the parties' genuine dispute and does not focus on irrelevant facts in the Amended Complaint that have nothing to do with the alleged misrepresentations of Defendants.[5]

---

[4] In any event, as Defendants note, they cannot be held liable for fraud based on facts that were already known to the market, such as the fact that the FDA tightened standards after the pharmaceutical company Merck pulled Vioxx from the market over concerns over cardiovascular effects of Vioxx. (*See* Defs.' Br. 16.)

[5] For example, Plaintiffs allege in the Amended Complaint that a physician being used as a "confidential witness" was unsure how commercially successful Trexima would be, given that there would be problems getting insurance companies to pay for an expensive proprietary combination of triptan with a NSAID rather than two generic drugs

Defendants' Alleged Failure to Disclose Specific Material Facts regarding the Results of the Two *In Vitro* Studies regarding Genotoxicity

It is well settled that there can be no liability under Rule 10b-5 in the absence of a false statement or an omission of a material fact. A defendant must make "a public misrepresentation for which it may be found primarily liable." *Gariety v. Grant Thornton, LLP*, 368 F.3d 356, 369 (4th Cir. 2004). Furthermore, where plaintiffs allege that a defendant omitted material information, they must identify specific public statements and identify how any omitted facts render those statements misleading. *See Longman v. Food Lion, Inc.*, 197 F.3d 675, 682 (4th Cir. 1999). Finally, a plaintiff cannot bring a claim for securities fraud based on the omission of information that was already known to the market. *Id.* at 684.

Here, Plaintiffs first contend that, throughout the Class Period, Defendants failed to disclose that the FDA issued the June 2006 Approvable Letter in part because of genotoxicity concerns raised by the findings in the First CHO Study. (*See* Amended Compl. ¶¶ 88-95.) Plaintiffs further allege that Defendants also concealed from the investing public that, as a result of the FDA's concerns, additional genotoxicity tests were to be conducted–and that the FDA had made clear that those tests were a precondition to Trexima approval. (*Id.* ¶¶ 68-69.) Plaintiffs

---

independently. (*See* Amended Compl. ¶ 81.) In their brief opposing the motion to dismiss, Plaintiffs do not address Defendants' contention that Plaintiffs fail to tie this fact to any alleged misrepresentation or failure to disclose by Defendants, or how it is otherwise relevant to Defendants' alleged misrepresentations regarding the genotoxicity test results and the anticipated approval date of August 2007.

note that by October 2006, Defendants knew that the Second CHO's Study's results replicated those yielded in the First CHO Study. In other words, the Second CHO Study was also positive for genotoxicity (i.e., potentially cancer causing). Plaintiffs allege that Defendants concealed these material facts from investors by failing to disclose these findings, and even assured investors that, among other things, the FDA had not expressed *any concern* regarding the long-term safety of Trexima, and that the data submitted in response to the June 2006 Approvable Letter had in fact *strengthened* Trexima's chances for FDA approval. (*Id.* ¶¶ 100, 107-08, 112-13, 121-22.)

Plaintiffs contend that Defendants' disclosure that "two *in vitro* nonclinical studies are being conducted and those results will be included in the response [to the June 2006 FDA Approvable Letter]" could not have alerted investors of the FDA's genotoxicity concerns with respect to Trexima or that the two *in vitro* studies were a consequence of those concerns, let alone that the studies were even being conducted to study genotoxicity. Plaintiffs note that medical researchers conduct a wide array of *in vitro* nonclinical studies to evaluate issues other than genotoxicity. Plaintiffs further note that Defendants "do not, and cannot, point to a single securities analyst report or statement by a market professional to support their contention that the market understood that the purpose of the *in vitro* tests was to study the genotoxicity of Trexima." (Pls.' Br. 14.)

Plaintiffs further allege that Defendants continued to inform investors that they expected the FDA to approve Trexima on August 1, 2007 (the FDA action date), and that Pozen would at that time receive $20 million in milestone payments along with royalty payments from GSK, which would have amounted to around 40 percent of Pozen's full-year revenue for 2007. (*Id.* ¶¶ 100, 108, 111-12, 121.) Plaintiffs allege that as a result of these materially misleading statements, "the market was all but certain that the FDA would grant the NDA application for Trexima by August 2007." (Pls.' Br. 5.)

Plaintiffs contend that Pozen "shocked" the investment community by issuing a press release before the market opened on August 2, 2007, announcing that, rather than approving the NDA for Trexima, the FDA has issued a second Approvable Letter for Trexima. (*See* Amended Compl. ¶ 133.) Plaintiffs note that during the Company's August 2, 2007, conference call, investors and analysts learned for the first time that the FDA had issued the June 2006 Approvable Letter in part because of genotoxicity concerns arising out of the positive test result from the First CHO Study. (*Id.* ¶ 136.) During that same conference call, Defendants also disclosed for the first time that the results observed in the Second CHO Study had corroborated concerns about genotoxicity. (*Id.*) Plaintiffs contend that although the market was shocked by these revelations, Defendants acknowledged that the genotoxicity issue was not a surprise to them. (*See id.*)

Plaintiffs contend that the language set forth in Pozen's quarterly report filed with the SEC just days after the FDA issued the second Approvable Letter on August 1, 2007, highlights Defendants' failure to disclose the FDA's genotoxicity concerns during the Class Period. Plaintiffs note that, in contrast to Pozen's quarterly reports filed with the SEC during the Class Period, the Company's Form 10-Q filed with the SEC on August 7, 2007, includes explicit language concerning the FDA's genotoxicity concerns:

> The FDA has expressed concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan. The companies intend to request a meeting with the FDA as quickly as possible to discuss the steps necessary to address the FDA's concerns. However, until we meet with the FDA, it is unknown if we will be able to adequately address their concerns.

(*See* Pls.' Ex. 2 to Bernstein Decl., at 29, docket no. 63.) Plaintiffs note that, notwithstanding that these concerns were identical to the FDA's genotoxicity concerns that gave rise to the June 2006 Approvable Letter, at no point during the Class Period did Defendants disclose those initial concerns to investors. Plaintiffs note, furthermore, that although Defendants announced in October 2006 that they had received the results from the two *in vitro* nonclinical studies and that they were submitting them to the FDA, Defendants not only concealed those findings from investors, but also failed to disclose then and throughout the Class Period that the

results from the Second CHO Study were identical to the findings observed in the First CHO Study.

Plaintiffs' Contention that Defendants Made Affirmative Misstatements Concerning Trexima's Safety Profile and the Genotoxicity Concerns Expressed by the FDA

Plaintiffs further contend that Defendants made specific, unqualified statements during the Class Period that misrepresented the FDA's concerns over the long-term safety of Trexima and, consequently, the time line for the drug's approval. Plaintiffs point to the statement by Defendant CEO Plachetka confirming an "assessment" by an analyst during an October 31, 2006, conference call "that the FDA has in fact not expressed any concern regarding the long-term safety of Trexima." (*See* Amended Compl. ¶ 100.) Plaintiffs point to additional, affirmative misstatements by Defendants that led investors to believe that additional safety information, including the results of the *in vitro* studies, that Pozen was submitting in response to the June 2006 Approvable Letter strengthened Trexima's NDA application. Plaintiffs contend that these statements were false and misleading because, in truth, the FDA had informed Defendants of their long-term safety concerns over Trexima (i.e., concerns over cancer), which were due to the genotoxicity findings observed in the First CHO Study, which were then replicated in the Second CHO Study. Plaintiffs contend that it is "incomprehensible how Defendants could have had a good faith belief that the FDA would approve Trexima in mid-2007 when the genotoxicity data observed in the Second CHO Study

replicated the initial results." (*See* Pls.' Br. 19.) Plaintiffs note that, nevertheless, Defendants continued to falsely assure the market throughout the Class Period that, among other things, they "believed" Trexima was "on track" for launch in the second half of 2007, and that they "expected" revenue "for the 2007 to be in the range of $50 million to $55 million," which included the $20 million in revenue from milestone payments from GSK for Trexima. (*See id.* ¶¶ 100, 112, 121.) Plaintiffs contend, therefore, that they have alleged with great particularity why Defendants' alleged stated beliefs, including those concerning the likelihood that the FDA would approve Trexima in mid-2007 and resulting revenues that would flow to Pozen, lacked a reasonable basis when made and were undermined by facts Defendants knew or recklessly disregarded. Plaintiffs allege that these statements are clearly actionable under the federal securities laws.

Plaintiffs' Allegations of Scienter

In addition to showing misrepresentation, a plaintiff must also allege scienter in a securities fraud case. Plaintiffs contend that the Amended Complaint alleges particularized facts evidencing Defendants' actual knowledge or reckless disregard of the falsity of their statements regarding the FDA's concerns over the genotoxicity issue and the impact of the genotoxicity tests on the time line for Trexima's approval. Plaintiffs contend, for instance, that the Amended Complaint details how Defendants had actual knowledge of the genotoxicity issue; were informed by the FDA that it viewed the genotoxicity issue as a significant impediment to approval; and were

aware that Trexima had virtually no chance of being approved by mid-2007 in light of the fact that the genotoxicity findings observed in the Second CHO Study replicated the results seen in the First CHO Study. Plaintiffs contend that these allegations clearly establish Defendants' scienter.

Plaintiffs further contend that Trexima's fundamental importance to Pozen's financial condition and prospects compels a powerful inference that the Company's senior management knew that Trexima's significant genotoxicity risks made it highly unlikely that the FDA would approve Trexima in August 2007. Plaintiffs contend that the individual Defendants' positions in Pozen, as senior executive officers who were closely involved with and had direct responsibility for important issues affecting the Company's business, support a strong inference of scienter.

Plaintiffs further contend that the stock sales by the Company's CEO Defendant Plachetka further support a strong inference of scienter.[6] Plaintiffs contend that the sheer magnitude of sales of Pozen stock by Plachetka–280,000 shares of Pozen stock for almost $4.54 million and the significant percentage (28 percent) of Plachetka's common stock holdings that he sold (in relation to the common stock holdings that he was authorized to sell during the Class Period) give rise to a strong inference of scienter. Plaintiffs maintain that the fact that Plachetka's stock sales were governed by the terms of a Rule 10b5-1 trading plan supports a

[6] The Amended Complaint also points to stock sales by former Defendant Wise as evidence of alleged scienter, but Plaintiffs have voluntarily dismissed Wise as a Defendant.

strong inference of scienter because the plan provided Defendants with a specific motive to conceal the truth concerning the genotoxicity issue from investors. That is, Plaintiffs contend that Plachetka was able to sell a substantial number of Pozen shares because, as a result of Defendants' material misrepresentations throughout most of the Class Period, the price of Pozen stock traded at prices higher than $15, i.e., the trigger price authorizing Plachetka to sell Pozen stock under the plan. Plaintiffs contend that, notably, since Defendants revealed the truth concerning Trexima and the regulatory review process on August 2, 2007, Plachetka has been precluded from selling his shares as the price of Pozen stock has remained under $15. Plaintiffs further note that on August 1, 2007, the trading day before Pozen disclosed that the FDA had issued the second Approvable Letter, Defendant Plachetka sold more than 30,000 of his shares of Pozen stock for more than $517,000.

ANALYSIS

For the following reasons, I find that Plaintiffs have failed to state a claim for securities fraud. First, Plaintiffs have failed to plead a requisite element–that Defendants made a false or misleading statement, or failed to disclose material information about the timing of the FDA's approval of Trexima. As to Plaintiffs' allegations regarding Defendants' alleged failure to sufficiently disclose the results of the two *in vitro* genotoxicity tests, Defendants contend that Plaintiffs' securities fraud claim here "boils down to" the complaint that Defendants used the word

"safety" rather than "genotoxicity" to describe the FDA's concerns in the June 2006 Approvable Letter. On this point, it is true that Defendants could certainly have provided more details when discussing the *in vitro* studies. As Defendants note, however, there is no requirement to use any particular words as long as the words are accurate and not misleading. *See Inspire Pharms.*, 515 F. Supp. 2d at 638. Defendants did not have a duty to disclose every detail of its FDA correspondence or to use any specific words in their disclosures. Rule 10b-5 requires disclosure only when the omitted information would render other affirmative statements misleading or false. *Taylor v. First Union Corp. of S.C.*, 857 F.2d 240, 243-44 (4th Cir. 1988). Here, Plaintiffs have failed to identify any reason why a "genotoxicity" concern is more or less serious than any other "safety" concern raised by the FDA, nor have Plaintiffs alleged any facts showing that genotoxicity concerns have particular adverse consequences for a drug's approval. Therefore, Defendants' failure to offer more details about the genotoxicity test results was not misleading.

Moreover, Defendants *did* warn the market that preclinical testing had raised various safety concerns generally, even before the Class Period, and they also repeatedly warned that FDA approval of Trexima was not guaranteed and could be delayed. Pozen's Form 10-Q filed with the SEC on November 13, 2002, disclosed that "recent results from a genotoxicity study involving MT 400 may require us to conduct chronic toxicology and carcinogenicity studies." (Defs.' Ex. 1 to Porritt Decl., at 9.) Pozen provided updated versions of this disclosure in every subsequent

periodic SEC report. Pozen's SEC filings also included extensive warnings about the FDA approval process, including warnings that "there can be no guarantee that the FDA will approve our NDA based on the information contained in our response to the approvable letter, or at all," and that there are "no guarantees . . . that additional testing will not be required for approval." (*See* Ex. 13, at 13, 25, 30; Ex. 16, at 13, 27, 32.)

When the FDA informed Pozen during their July 26, 2006, meeting that it would require Pozen to conduct additional genotoxicity studies, Defendants promptly disclosed this fact. In the August 3, 2006, conference call, Defendant Plachetka stated that "two in vitro nonclinical studies are being conducted and those results will be included in the response also." (Amended Compl. ¶ 92.) Dr. Plachetka told investors during the August 3, 2006, call that "[o]f course, there is never any guarantee that this response will be adequate and it's always possible that additional questions could arise during [the FDA's] review." (*Id*.) Pozen repeated the disclosure regarding the two *in vitro* studies during an October 31, 2006, investor conference call. (*Id.* ¶ 100.) Furthermore, in both a December 13, 2006, press release and conference call, Defendant Marshall Reese stated, "[t]here is no certainty that these revisions coupled with the original NDA will lead to approval of the Trexima NDA." (*Id*. ¶¶ 107, 108; *see also id.* ¶¶ 92, 112.)

As Defendants note, the market was, therefore, aware that Trexima's preclinical studies had raised safety concerns, that Pozen was conducting additional

in vitro studies to submit to the FDA in response to the June 2006 Approvable Letter, and that there was no guarantee that the FDA would accept this data, meaning that additional testing might be necessary. Plaintiffs' allegation that Pozen withheld this information, therefore, has no merit, as there can be no claim for securities fraud where allegedly concealed facts have already been disclosed publicly. *See Longman*, 197 F.3d at 684; *Inspire*, 515 F. Supp. 2d at 637.

The crux of Plaintiffs' securities fraud claim is that Defendants made false statements regarding *when*, not *if*, the FDA would approve Trexima. Significantly, however, Plaintiffs allege no facts to support their allegation that because of the CHO test results it was highly unlikely that the FDA would approve Trexima in August 2007. Therefore, Defendants' failure to offer more details with regard to the CHO test results does not render misleading their anticipatory statements about when Trexima would be approved. In other words, Plaintiffs have alleged *no specific facts* to support their blanket assertions that "it is incomprehensible how Defendants could have had a good faith belief that the FDA would approve Trexima in mid-2007," or that the FDA had "informed [Defendants] that it viewed the genotoxicity issue as a significant impediment to approval" so that "Trexima had virtually no chance of being approved by mid-2007," or that Defendants "must have known" the preclinical data would not support FDA approval in 2007. (*See* Reply. Br. 6, quoting Pls.' Br. Opp. 17, 18-19, 21-22.) Contrary to Plaintiffs' assertions, Defendants' opinion that Trexima could be approved in August 2007 did have a reasonable basis.

As Defendants note, the relevant FDA Guidelines expressly permitted FDA approval of Trexima despite the positive results of the two CHO studies, and it is undisputed that the FDA ultimately *did* approve Trexima, despite the two positive results. Here, Plaintiffs assert that the FDA expressed grave concerns over the long-term safety of Trexima because of the positive results of the CHO study, but the record reveals no such statements by the FDA. Based on the FDA's own guidelines, merely requiring further studies on the genotoxicity issue in the face of a positive CHO is not necessarily a warning bell by the FDA that the drug will not be approved because of long-term safety issues. To this extent, the facts in this case are different from cases in which the FDA had indicated to the defendants that it was not going to approve the NDA at issue. For example, in *In re Connetics Corp. Sec. Litig*., No. C 07-02940 SI, 2008 WL 3842938 (N.D. Cal. Aug. 14, 2008), the plaintiffs alleged specific facts showing that a drug candidate was highly unlikely to be approved based on its preclinical testing results, including an opinion from an expert panel that "they did not know of any drug that exhibited [similar results] that had ever been approved by the FDA." *Id*. at *1. Other allegations included specific facts regarding a conference between the drug company and the FDA where the FDA communicated "serious concerns" about the drug. *Id.* at *7. The FDA ultimately did not approve the drug. Under these specific facts, the court concluded that the company's statements that the drug was safe were incomplete and inaccurate. *Id.* at *7-8. Such specific allegations are wholly absent here. Here, Plaintiffs do not allege anywhere that the

FDA has ever failed to approve a drug that yielded positive results from two CHO studies where two other studies (the mouse lymphoma assays) had yielded negative results, and here the FDA ultimately approved Trexima in April 2008. In sum, because Plaintiffs' assertions are not supported by any facts, let alone *particularized* facts, they are entitled to no weight. *See Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 174 (4th Cir. 2007).

In any event, most of the challenged statements are forward-looking statements about Defendants' expectations regarding the timing of the FDA approval process and what revenue Pozen would receive *if* Trexima were approved in 2007. As noted above, under the PSLRA's Safe Harbor provision, forward-looking statements are immunized from liability if they contain "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement[s]." 15 U.S.C. ¶ 78u-5(c)(1)(A)(i). Even if a forward-looking statement is not accompanied by cautionary language, liability *only* attaches if the speaker had *actual* knowledge that it was false when made. *Id.* § 78u-5(c)(1)(B)(i); *see also In re Lab. Corp. of Am. Holdings Sec. Litig.*, No. 1:03CV591, 2006 WL 1367428, at *3 (M.D.N.C. May 18, 2006). Furthermore, even before the Safe Harbor provision was passed, the Fourth Circuit had held that forward-looking statements are not actionable if they do not guarantee any particular results. *See Raab*, 4 F.3d at 290.

The forward-looking statements at issue here fall into two categories: (1) those forecasting when Pozen would submit its response to the June 2006 Approvable Letter and when and how the FDA might respond; and (2) those forecasting the launch dates for Trexima and sales and revenues in the event that the FDA approved Trexima. These statements expressly warn that there was no guarantee that the FDA would accept Pozen's submission. Furthermore, Defendants' forward-looking statements were accompanied by meaningful, cautionary language, and Plaintiffs have not shown that Defendants had any actual knowledge that the statements were false when made. As I have already discussed, Plaintiffs have failed to sufficiently allege facts showing that Defendants had reason to believe that the FDA would *not* approve Trexima in August 2007.

Furthermore, as to Plaintiffs' contention that Defendants' cautionary statements were not meaningful because they were merely boilerplate, this argument has no merit. Cautionary language is meaningful if it is "enough to properly warn an investor of significant risks similar to that actually realized so as to put the investor on notice." *Lab. Corp.*, 2006 WL 1367428, at *5. Here, Defendants specifically warned in their forward-looking statements that preclinical data had raised genotoxicity concerns as to Trexima that could cause developmental delays and increased expenses and that the preclinical data could cause the FDA to deny or delay approval of Trexima due to differing interpretations of the FDA guidance. (*See* Defs.' Mem. at 20-21.)

Plaintiffs contend, however, that some of the challenged statements, including statements regarding the anticipated launch date of August 2007, are not "forward-looking" because they were based on concealment of then-existing facts–for instance, that the June 2006 Approvable Letter was based, at least in part, on the FDA's genotoxicity concerns (Amended Compl. ¶¶ 66-68); that the FDA required additional genotoxicity testing as a precondition to Trexima's approval (*Id.* ¶¶ 60, 92, 100, 133, 136); and that the genotoxicity findings observed in the Second CHO Study replicated the results seen in the First CHO Study, compelling the FDA to issue the June 2006 Approvable Letter (*Id.* ¶¶ 66, 68, 133, 136). According to Plaintiffs, Defendants concealed these facts while at the same time making misleading statements concerning Trexima's safety record, Defendants' communications with the FDA with respect to that record, and the data that Pozen was submitting in response to the June 2006 Approvable Letter. Plaintiffs contend that these statements concealed historic facts about Trexima and are, therefore, not "forward-looking."

Plaintiffs' argument fails, as "[t]he statutory definition of 'forward-looking statement' does not refer at all to the defendants' knowledge of the truth or falsity of the statement." *Harris v. Ivax Corp*., 182 F.3d 799, 807 n.10 (11th Cir. 1999). Thus, whether a statement is forward-looking is determined by examining the statement, not the fact allegedly omitted. Indeed, as Defendants note, to accept Plaintiffs' argument would swallow the entire Safe Harbor provision of the PSLRA, as well as

pre-existing Fourth Circuit law regarding forward-looking statements, because any claim based on forward-looking statements can be characterized as a claim about omissions of existing facts. *See Marsh Group v. Prime Retail, Inc.,* 46 Fed. Appx. 140, 146-47 (4th Cir. 2002). In sum, for all these reasons, Plaintiffs have failed to show that Defendants either misrepresented material facts or failed to disclose material facts regarding the results of the two *in vitro* studies involving genotoxicity and the anticipated approval date for Trexima.

The only other factual statements Plaintiffs specifically mention in their brief opposing the motion to dismiss have nothing to do with genotoxicity and, therefore, cannot create any duty to disclose additional information about preclinical genotoxicity testing. For instance, Plaintiffs allege that Defendant Plachetka stated in a conference call that the FDA had not requested any long-term *cardiovascular* studies. (*See* Amended Compl. ¶ 100.) Defendants contend that this was a correct statement and, furthermore, that the FDA had never requested any long-term genotoxicity studies either. In any event, this statement is immaterial to Plaintiffs' claim of fraud based on Defendants' alleged misrepresentations regarding the two *in vitro* genotoxicity studies.

Plaintiffs also refer to a statement by Defendant Plachetka in which he opined that Trexima had an "unblemished" record. As Defendants note, this quote was taken from a lengthy exchange between several Defendants and an analyst regarding how GSK planned to market the drug, in which Plachetka described the

fact that Trexima had beaten its component drug, Imitrex, in head-to-head trials. (*See* Amended Compl. ¶ 113.) Neither of these statements constitute "false" statements. Furthermore, using a mere descriptive term such as "unblemished" is simply too vague to constitute a statement of material fact. It is well settled that indefinite statements of corporate optimism, also known as "puffery," are immaterial as a matter of law. *See Raab,* 4 F.3d at 289.

In addition to the fact that Plaintiffs have not alleged sufficient facts showing how Defendants made false or misleading statements, after applying the heightened pleading standards of the PSLRA, I also find that Plaintiffs' claims fail because Plaintiffs have not established a strong inference of scienter. Plaintiffs contend that Defendants did not discuss more specifically the genotoxicity test results because they were intentionally trying to mislead investors about the likelihood of Trexima being approved in August 2007, if at all. It is more compelling, however, to infer that Defendants merely viewed the positive results of the CHO study as minor and that they honestly believed that the positive results would not pose a barrier to approval in August 2007. As already noted, an FDA guidance document regarding genotoxicity states that "a positive finding in an in vitro chromosomal aberration assay that is not corroborated by the matching exposure regimen of *the mouse lymphoma assay* could also call into question the significance of the positive finding." (*See* Defs.' Ex. 6 to Porritt Decl., at 3.) As Defendants explain, because the mouse lymphoma assay is considered to be the most reliable test, a negative result–such

as the one here–may counter a positive CHO test result, and the weight of evidence would therefore support approval of the drug. In other words, a positive result in one of the genotoxicity tests does not necessarily doom approval of a drug as potentially cancer causing. Therefore, one may plausibly infer that Defendants did not more specifically discuss the genotoxicity tests because they did not consider them to be impediments to approval; Defendants may simply have viewed the genotoxicity issue as minor, given the FDA guidance. Defendants have themselves stated that they always considered the positive results in the CHO studies to be an "anomaly."

Therefore, I agree with Defendants that the FDA guidance supports a completely plausible inference of non-culpable conduct because it shows that Defendants had a reasonable basis to believe the FDA would find Pozen's 2006 submittal of genotoxicity data to be sufficient and that Trexima would be approved on the anticipated date of August 2007.[7] *See Constr. Laborers Pension Trust v. Neurocrine Biosciences, Inc.*, No. 07CV1111-IEG-RBB, 2008 WL 2053733, at *6-7 (S.D. Cal. May 13, 2008) (stating that an FDA guidance document supported an inference of non-culpable conduct).

Here, Plaintiffs' theory of scienter rests primarily on Defendant Plachetka's statement during the August 2, 2007, investor conference call that the genotoxicity

[7] Plaintiffs' assertion that the guidance document raises factual questions that cannot be resolved at the motion to dismiss stage ignores their pleading burden, which is to plead facts supporting an inference of scienter that is "cogent and compelling" in the face of "plausible nonculpable explanations for the defendant's conduct." *Tellabs*, 127 S. Ct. at 2510.

issue "wasn't a surprise." (*See* Pls.' Opp. Br. 21.) As Defendants note, however, in this conversation Plachetka was referring to the FDA's genotoxicity concerns and not to any expectation that the FDA would request additional data in August 2007. Defendant Plachetka stated that Pozen and its experts believed that the CHO test results were an anomaly caused by idiosyncrasies in the CHO test procedure while other, more reliable, tests showed no genotoxicity issues. (*See* Amended Compl. ¶ 136.) More specifically, in the conference call dated August 2, 2007, Plachetka stated, in pertinent part, in discussing the two *in vitro* studies:

> [I]t was our interpretation that as the Agency asked us to do a second test and we already had another–I think we had another two already in the NDA that were negative, that if we ended up confirming that this was unique to the CHO test, which it appears to be unique to the CHO test, and negative in the other three tests that our experts and GSK's experts are saying *that is just an anomaly of the way that the compound interacts in that particular test*.
>
> *And it does not foreshadow that this is going to be a problematic situation.* And I think as I mentioned before, there are a high degree of positives in a particular test, but what the Agency has written about in their own guidance is that they look at where there is confirming gene toxicity in more than one test.
>
> So I don't want to say that this was a surprise. It wasn't a surprise. *We knew this was there, but we also thought that this was not as important as the clinical issues [i.e., the cardiovascular test] because [the FDA] had spent most of their time talking about the clinical issue and because we had all of these offsetting negative results. . . . . [T]he new test that we did was called the mouse lymphoma test, and it was negative, but the study that was positive in our NDA, the [CHO] test which they cited in their approvable letter, was reproducibly positive.* But again, we think that . . . is because during the course of this test as you raise the concentrations of the drugs, something kills the cells and that makes the data much more difficult to interpret.

> Now, I'm not a toxicologist and I don't want to start the discussion of what is right in the interpretation of data and how it all came about. *But reasonable scientists have looked at these data and said, gee, I don't think [this] really indicates chromosomal problems here. This looks to me to be unique to this particular test.*

(*Id.*) (emphasis added). As Dr. Plachetka's explanation here makes clear, although Defendants were aware of the results of the two genotoxicity studies, the Company nevertheless believed that it had sufficiently answered the FDA's genotoxicity concerns in 2006 and that Trexima would be approved in August 2007. (*See* Defs.' Ex. 26 to Porritt Decl., at 13, 15.) That is, Defendants did not admit that the FDA's failure to approve Trexima in August 2007 was not a surprise; rather, they merely admitted that the genotoxicity issues were not a surprise. In sum, Plaintiffs have failed to present facts showing that Defendants had advance knowledge that the FDA would not approve Trexima in August 2007.

In attempting to establish scienter, Plaintiffs also emphasize the fact that certain analysts expressed "shock" over the second Approvable Letter and that some analysts opined that Defendants had not been entirely "transparent" about the CHO studies regarding genotoxicity. Again, it is reasonable to infer that Defendants did not provide more details about the CHO studies because they considered the positive results to be "anomalies" and "trivial." In the August 2, 2007, conference call, Plachetka stated:

> And putting things in perspective, the cardiovascular safety issue *was the dominant issue by far during all our interactions with the [FDA]*

> since our first approvable letter, including our only face-to-face meeting with them last July.
>
> . . . .
>
> The in vitro studies that we conducted . . . were last year's suggestion by the FDA as to how to address this issue . . . . The one study confirmed the result which we felt and still feel is due to cytotoxicity in the assay probably unique to the two components which makes interpretation of the results funky.
>
> And then when you are in that situation it was our interpretation that the FDA said if that happens again, go to the next step and do what is known as a mouse lymphoma assay. If *that would have been positive, then we would have had to go back to the [FDA] and say, yes, you know there is a concern here. And then we will talk about what would go on. But in that circumstance[], that test was negative.*
>
> *And so we were here . . . with three negative gene tox tests, and one positive that we felt was an aberrancy, and unique to the situation we found for the two drugs*. But not indicative of a clastogenic effect of the product in the long-term exposure situation. *So we thought we'd adequately addressed it and the scientists that reviewed the situation told us that was a mainstream opinion*.

(*Id.*, Ex. 26, at 5, 17) (emphasis added). Based on this statement by Plachetka, it is reasonable to infer that Defendants were not recklessly or intentionally attempting to defraud investors by failing to disclose more details regarding the genotoxicity tests. Rather, it appears that Defendants simply did not consider the positive results to be a barrier to approval or even particularly ominous. Therefore, even if Defendants were less than "transparent" with regard to the genotoxicity tests, and even if the failure to disclose was misleading, Plaintiffs still cannot establish the essential element of scienter. That is, the more compelling inference here is that

Defendants acted innocently, or even negligently, with regard to disclosure of the genotoxicity tests, as opposed to acting recklessly or with fraudulent intent.

It is undisputed that Defendants here ultimately satisfied the FDA's concerns through a short-term clinical study after the 2007 Approvable Letter. Moreover, analysts did appear to understand *generally* that the FDA had expressed safety concerns that prompted the further preclinical testing, and courts have observed that analysts' claims, especially on matters involving scientific knowledge, are not always reliable. *See Inspire*, 515 F. Supp. 2d at 638 (observing that analysts are not scientists and that analysts' assertions as to scientific data were "well outside of their realm of knowledge and expertise). As already noted, Plaintiffs do not allege anywhere in the complaint, nor do they contend in their brief, that a positive test in a CHO study necessarily precludes FDA approval of a drug. Therefore, certain analysts' "surprise" over Defendants' failure to disclose the genotoxicity test results could have resulted from the analysts' own misunderstanding regarding the significance of the positive results. In other words, due to their lack of scientific expertise, analysts could have wrongly assumed that the positive results in the genotoxicity tests were more significant than they were–after all, in the end the FDA gave its approval despite the two positive test results. In sum, I do not find scienter based on certain analysts' opinions that Defendants were not as "transparent" as they should have been with regard to the genotoxicity results.

In any event, the most salient point is that Plaintiffs offer *no evidence* to show that Defendants doubted that the FDA would approve Trexima in August 2007, or that they had any indication themselves that the FDA would require more information after the results of the Second CHO study were submitted. Therefore, even if Defendants had disclosed every single detail about the two *in vitro* studies, Plaintiffs have alleged no facts to show that Defendants' statements regarding their anticipated launch date of August 2007 and their anticipated revenues for 2007 would have been any different. This fact is important because Plaintiffs are claiming damages arising out of Defendants' statements regarding the anticipated approval date of August 1, 2007, and the FDA's failure to approve Trexima on that date. Finally, Defendants point out that if they had known in 2006 that the FDA would require an additional study beyond the Second CHO study, Pozen would have conducted the study then, therefore speeding up FDA approval. Indeed, this argument makes sense because Trexima's commercial success depended, in part, on entering the marketplace well before the patent on Imitrex expired so that GSK would have time to switch its Imitrex customers to Trexima. *Accord Cozzarelli*, 549 F.3d at 627 ("It is improbable that [Defendant] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure.").

I further find that the mere fact that Defendant Plachetka sold stock during the Class Period does not give rise to an inference of scienter in this case, given the amount that he sold. For stock sales to support an inference of scienter, the timing

and amount must be "unusual and suspicious." *Hunter*, 477 F.3d at 184. As Defendants note, Plachetka sold only 6.7 percent of his Pozen stock; his sales were made pursuant to a Rule 10b5-1 plan; and the two remaining individual Defendants, William Hodges and Marshall Reese, did not sell any stock.[8] Therefore, the stock sales here were neither unusual nor suspicious. *See In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 390 (4th Cir. 2005) (stating that sales by the defendants of 13 percent or less of their total holdings were not "unusual or suspicious" but were "nearly *de minimis*"); *Inspire*, 515 F. Supp. 2d at 640 (stating that sales of "only 12, 13, and 3 percent" did not support scienter).

Finally, in an attempt to show scienter, Plaintiffs point to the fact that Pozen is a small company and that its officers were integrally involved in all of its operations and therefore the individual Defendants must have known about the positive results from the two *in vitro* studies. I agree with Defendants that this fact is irrelevant, since the issue is not whether the individual Defendants knew about the genotoxicity test

[8] Plaintiffs argue that Defendant Plachetka sold "28%" of his shares based on the fact that his Rule 10b5-1 plan included 1,000,000 of his 4,177,134 total Pozen shares, and he sold 280,000 of those shares (the 1,000,000 Rule 10b5-1 shares) during the Class Period. As Defendants note, this calculation is incorrect because it reflects only the percentage of shares sold under Plachetka's Rule 10b5-1 plan and fails to account for all shares that were saleable during the Class Period. *See Inspire*, 515 F. Supp. 2d at 640 (taking into account total shares and vested options in determining the percentage of shares sold for purpose of establishing scienter). Plaintiffs also note that Plachetka sold some of his shares on August 1, 2007, the day that Pozen received the second Approvable Letter, and one day before Pozen disclosed the second Approvable Letter to the investing public. Although this fact could possibly implicate insider trading, it does not support Plaintiffs' theory that Plachetka knew before August 1, 2007, that the FDA was not going to approve Trexima on the anticipated date of August 1, 2007. Indeed, it appears to indicate the opposite.

results, but whether Defendants "knew" that there was "virtually no chance" that the FDA would approve Trexima in August 2007. In sum, the facts as a whole "more plausibly suggest that [Defendants] acted innocently–or even negligently–rather than with intent or severe recklessness." *Cozzarelli*, 549 F.3d at 625. Therefore, Plaintiffs have failed to sufficiently plead scienter to support a claim for securities fraud.

CONCLUSION

For all the reasons stated herein, it is therefore **RECOMMENDED** that the court **GRANT** the motion to dismiss the Amended Complaint filed by Defendants Reese, Hodges, Pozen, Plachetka, and Wise (docket no. 50). The separate motion to dismiss the Amended Complaint filed by Defendant Wise (docket no. 52) should be dismissed as **MOOT**, as Plaintiffs have filed a notice of voluntary dismissal as to Defendant Wise, *see* note 1. Furthermore, Plaintiffs' motion to strike (docket no. 59) is **DENIED**. To the extent that Plaintiffs have requested alternatively in their brief that the court allow Plaintiffs to amend the Amended Complaint to redraft the complaint to get over the pleading hurdles of Rule 12(b)(6) and the PSLRA, the motion should be **DENIED** as futile. Finally, Defendants' request for oral argument

on the motion to dismiss pursuant to the court's Local Rule 7.3(c)(1) (docket no. 58) is **DENIED**.

WALLACE W. DIXON
United States Magistrate Judge

February 19, 2009